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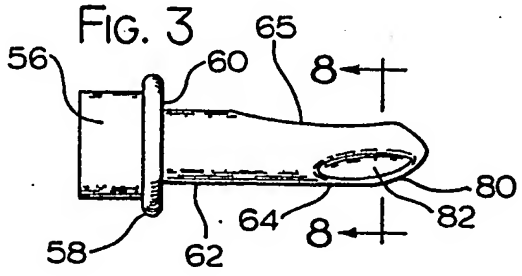
(54) **Medical tube.**

(57) A cannula for insertion into a body incision is provided with a tip (54) having an opening (65) in the sidewall and a pair of recesses (82, 84) in the outer surface of the tip defining a longitudinally extending ridge (80). The ridge (80) facilitates insertion of the tip (54) by gradually dilating the incision.

FIG. 3



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Description

Medical Tube

This invention relates to a medical tube and more particularly to a tip for an aortic cannula.

Aortic cannulas are used during cardiac surgery to convey blood from an extracorporeal circulation system to the aorta. An aortic cannula can, for example, be employed in a total bypass so that the heart or other organs and vessels can be operated on in a substantially dry state.

An aortic cannula generally comprises a flexible tube having a relatively rigid tip which is forced through an incision in the wall of the aorta. It is important that the incision is no larger than absolutely necessary to minimise leakage and the subsequent healing time.

Other medical tubes, for example for insertion into other blood vessels, have similar requirements.

One problem with conventional aortic cannulas is that the tip is rather difficult to insert through the aortic incision without causing damage to the aorta. Generally the tip is rounded and blunt to avoid cutting the aorta but the blunt tip may nevertheless traumatize the aorta wall as it is pushed through the incision. If the incision is made large enough to reduce trauma during insertion of the cannula tip, then there is of course, greater damage to the patient due to the enlarged incision, and such an incision requires a greater number of stitches and may have a longer healing time. The user has the choice of either risking considerable blood leakage by making a large incision or damaging the aorta due to the forces required to insert the cannula.

In some cases, open-ended cannulas are employed; with such cannulas the edge of the wall about the end opening tends to catch on the edge of the incision and damage the aorta. Some open-ended aortic cannulas have angled ends for effecting a change in the direction of blood flow from the cannula to the aorta. These angled end devices, however, must be manipulated for proper orientation during insertion and may cause further damage to the aorta.

Similar problems are encountered in the insertion of medical tubes into other vessels.

It is therefore an object of the present invention to provide a medical tube having an improved distal end adapted for insertion through an incision in a patient and wherein one or more of the above-mentioned problems or disadvantages are overcome.

According to the invention there is provided a tip for a medical tube and comprising a tubular member having proximal and distal openings for the passage of fluid therethrough, the tip having a longitudinally extending ridge on the outer periphery thereof, said ridge blending smoothly into the distal end of said tip.

The ridge ensures that the surgical incision into which the tip is placed is gradually dilated; this ensures minimum trauma to the patient since force required to insert the tip is reduced, and minimum blood loss since the incision is gradually stretched around the tip to give an improved seal. The tip allows the surgeon to make the incision smaller than hitherto whilst achieving a minimum level of patient trauma and blood loss.

The ridge may be defined by opposite recesses in the tip wall which are preferably eliptical in shape. All exterior surfaces of the tip blend smoothly into one another to ensure ease of insertion and minimuse the chance of cutting or tearing the area of the incision.

In the preferred embodiment the distal opening of the tip is on the opposite side to the ridge. The tip tapers radially inwardly at the distal end to a smoothly rounded blunt point. The tip lumen preferably blends smoothly from proximal to distal openings to ensure smooth blood flow and reduce hemolysis.

A peripheral flange may be provided on the tip to limit insertion through the incision; the flange may be secured to the area of the incision, by for example, sutures through holes therein.

The invention also provides a medical tube comprising a tube and the tip aforesaid. The tube is preferably connected to the proximal end of the tip and abuts a circular internal abutment so that the bore of the tube matches the bore of the tip lumen to ensure smooth blood flow therebetween.

Other features of the invention will be apparent from the following description of a preferred embodiment shown, by way of example only, in the accompanying drawings in which:-

Figure 1 is a diagrammatic illustration of a human heart and some associated blood vessels connected to an extracorporeal circulation system and including an aortic cannula having a tip according to the present invention;

Figure 2 is an elevation of the aortic cannula of Figure 1 with a proximal connector attached thereto;

Figure 3 is an enlarged elevation of the tip of the cannula shown in Figure 2;

Figure 4 is a top view of the cannula tip shown in Figure 3;

Figure 5 is a view of the underside of the cannula tip shown in Figure 3;

Figure 6 is a right end view of the tip as viewed in Figure 3;

Figure 7 is a cross-section along line 7-7 of Figure 5 and showing the tip attached to the cannula;

Figure 8 is a cross-section along line 8-8 of Figure 3;

Figure 9 is an enlarged plan view of a portion of the aorta shown in Figure 1 showing a suitable surgical incision;

Figures 10 and 11 illustrate one manner of inserting the tip into the incision of Figure 9.

Referring now to the drawings, and particularly to Figure 1, there is illustrated a portion of a surgical site 10 showing a heart 12, a right atrium 14, superior and inferior vena cavae 16 and 18 respectively, and an aorta 20 of a patient. A pair of vena caval

catheters 22 and 24 extend into the atrium 14 and into the vena cavae 16 and 18, respectively. The vena cavae may be tightened about the ends of the catheters 22 and 24 by suitable noose or the like as shown.

The opposite ends of the vena caval catheters 22 and 24 are connected through a Y-connector 26 and tube 30 to the inlet of an extracorporeal circulation system 28. The extracorporeal system may include a blood oxygenator, a blood pump, filters, bubble removing apparatus, and a defoamer. System 28 serves as an artificial heart and lung, changing venous blood into oxygenated blood. A tube 32 connects the outlet side of the circulation system 28 via a tube connector 34 to an aortic cannula 36, shown inserted into the aorta 20, for returning oxygenated blood to the arterial system of the patient. The extracorporeal circulation system in Figure 1, completely bypasses the heart so that the heart or associated organs and vessels may be operated on in a substantially dry state.

The aortic cannula 36, as seen in Figure 2, includes a tube 38 tapering slightly from the proximal or left end 40 radially inwardly in the distal direction. A hollow tube connector 34 has one end inserted into the proximal end 40 in tight sealing engagement. A removable end cap 46 is shown in sealing engagement in the proximal end of connector 34. The cap 46 is shown having a passage 47 extending therethrough; a hydrophobic filter 48 covers the distal end of passage 47 while the proximal end of the passage is open to the atmosphere. The cap 46, as will be further described, allows air in the cannula 36 to be purged during insertion procedures but will not allow blood to pass. The connector 34 is provided with a side port 49 that is shown closed by a cap 50 which is tethered by a resilient strap 51 having an eyelet 52 surrounding the connector 34. The port 49 may be provided with a female luer taper for connection to other apparatus, for example, for bloodsampling. The port 49 may be provided with conventional luer lock ears and the inner wall of cap 50 provided with complementary luer lock threads so that cap 50 can be threaded onto and off of connector 34 as desired.

Cannula 36 includes a tip 54 connected to the distal end 42 of tube 38. Preferably, tip 54 is formed or moulded as a separate plastic element and attached to the tube 38. The tube 38 may be made of any suitable plastic or rubber; preferably one that is flexible enough to allow some bending but which does not easily kink and occlude the fluid passage when moderate bending forces are applied to it, such as during the connection of the cannula in the circulation system. Tube 38 may be formed of, for example, polyvinyl chloride. The tip 54 may also be formed of any suitable material, for example, the same material as tube 38 but preferably of a somewhat harder or more rigid grade so that it can be inserted into the aorta without bending. Tip 54 may be moulded, for example, from a relatively rigid polyvinyl chloride.

Referring especially to Figures 3 to 8, tip 54 comprises an annular collar 56 having a circular flange 58 that has a distally facing flat side 60 and may be provided with suture slots if desired for securing the tip to the aorta. Collar 56 is integrally connected with a distally extending, generally cylindrical portion 62 of the tip which smoothly connects with a distal end portion 64. An elongate or generally elliptical opening 65 (Figure 4) is provided through the wall of the tip. As best seen in Figure 7, the distal end portion 42 of tube 38 is shown extending into collar 56 and engaging an inner radially inwardly extending circular wall or land 66. The wall 66 and the outer wall of the tube 38 may be fixed together, such as by an adhesive, solvent bonding, or by other suitable means. Preferably, and as shown for illustration in Figure 7, the thickness of the sidewall of tube 38 at the distal end is substantially the same as the width of the circular wall 66 so that the tube lumen, indicated at 70, and the lumen of the cylindrical portion 62 of the tip, indicated at 72, are substantially the same diameter so as to provide a smooth transition for blood flow from the tube 38 to the tip 54.

The distal end portion 64 has an inner preferably smoothly curving wall 74 (Figure 7) extending between the inner wall of the cylindrical portion 62 and the distal end of opening 65 so that blood flowing distally in lumen 70 flows into the tip 54 and out the opening 65 with minimal turbulence even though there is a substantial angluar change in the direction of blood flow. The wall 74 closes the distal end of the tip 54 and directs the flow of blood out of opening 65.

The distal end portion 64 is provided with a smoothly contoured ridge 80 in the outer surface of the tip formed by two smoothly curving generally elliptical cavities or recesses 82 and 84 in the outer surface of the tip on opposite sides and adjacent the ridge 80; the recesses are symmetrical. Ridge 80 smoothly blends into the cylindrical portion 62 of the tip as well as the distal extremity of the tip. The ridge 80 and recesses 82 and 84 have smoothly curving edges as best seen in Figure 8 and the outer surface of the tip is consequently free of any sharp edge. The edge of the opening 65 may be radiused or rounded to smoothly blend with the outer surface of the tip. The major axis of the recesses 82 and 84 extends longitudinally of the tip and curves radially inwardly toward the distal end. In this way, the exterior surfaces of the tip adjacent each side of the ridge 80 taper radially inwardly toward the distal end. The radially outermost surface of the ridge 80, as best seen in Figure 3 and 7, is coextensive with the outer surface of the cylindrical portion 62 of the tip.

Preparatory to insertion, an incision or a slit 86, as shown in Figure 9, may be made in the aorta 20. In use the cannula is held with ridge 80 at the bottom of the tip as shown in Figure 10; the ridge is moved toward the slit with the cannula being held at an angle to the longitudinal axis of the aorta. As the ridge enter the slit, the slit is opened gradually or dilated until the entire tip penetrates the wall of the aorta. The cannula is then moved into the aorta until the annular distal side 60 of the flange 58 engages the outer surface of the aorta as shown in Figure 11. The flange 58 may be sutured to the aorta.

Upon insertion of the tip into the aorta 20, blood

from the aorta flows into the cannula 36 displacing the air in the cannula 36 and causing the air to flow through the filter passage 47 to the atmosphere. The hydrophobic filter 48 will not allow blood to pass. With the air removed from the cannula, cap 46 is removed and the proximal end of connector 34 connected to the tube 32 (Figure 1). The tube 38 may conveniently be clamped off during removal of the cap and the connection of tube 32 to tube 38. If further air is found in the cannula 36 or connector 34, it may be vented from port 49.

By providing the longitudinally extending smoothly blending ridge 80, the ridge can be used as the leading edge of the cannula during insertion into the aorta so that the forces applied are more evenly distributed in spreading the walls of the incision thereby reducing trauma to the aorta and reducing blood loss. Upon insertion of the tip 54, the slit will tend to be dilated and conform closely to the outer wall of the cylindrical portion 62. The tip 38 not only reduces blood loss during insertion of the cannula but also reduces blood loss as the operation continues. By providing a smoothly curving lumen and eliminating sharp edges, blood can flow through the cannula with reduced hemolysis.

As various changes could be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description and apparatus shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

1. A tip (54) for a medical tube and comprising a tubular member having proximal and distal openings for the passage of fluid therethrough, the tip (54) having a longitudinally extending ridge (80) on the outer periphery thereof, said ridge blending smoothly into the distal end of said tip.

2. A tip according to Claim 1, wherein said ridge (80) is defined by opposite recesses (82, 84) in the tip wall.

3. A tip according to Claim 2, wherein said recesses (82, 84) are substantially eliptical.

4. A tip according to Claim 3, wherein the major axis of said recesses (82, 84) tapers toward the geometric centre of the tip in a distal direction.

5. A tip according to any preceding claim, wherein said ridge (80) is the sole longitudinally extending ridge on the tip.

6. A tip according to any preceding claim, wherein said distal opening (65) is in the sidewall of the tip and is the sole opening therein.

7. A tip according to any preceding claim, wherein said distal opening (65) is on the opposite side of the tip to said ridge (80).

8. A tip according to Claim 7, wherein the tip lumen (72) curves smoothly from the proximal opening to the distal end of the distal opening.

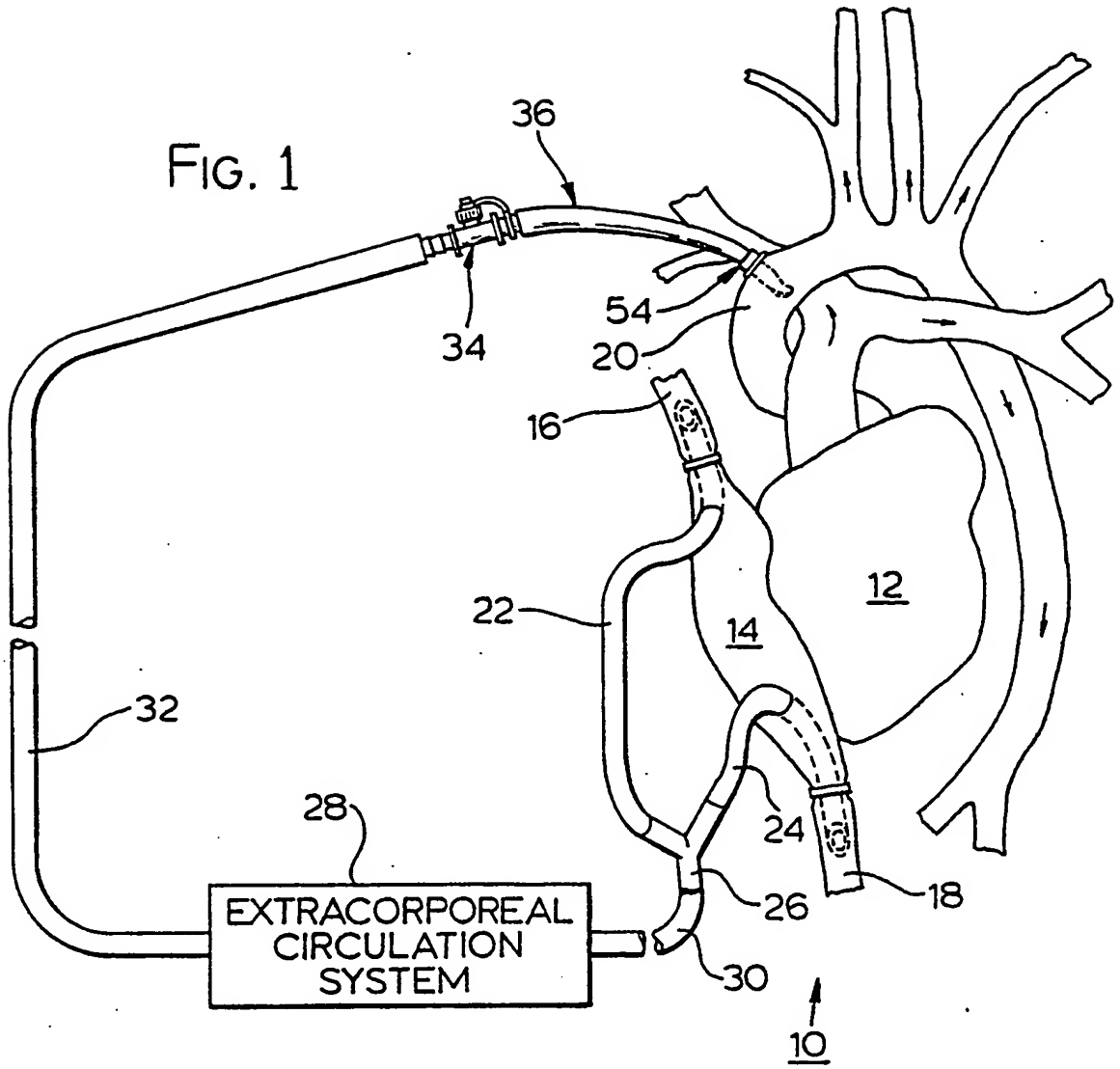
9. A tip according to Claim 8, and including a peripheral flange (58) to limit insertion of the tip into a body incision.

10. A tip according to Claim 9, wherein said flange (58) is intermediate the ends thereof.

11. A medical tube comprising a tube (38) having a tip (54) according to any preceding claim, wherein the tube is connected to the proximal end of the tip.

12. A medical tube according to Claim 11, wherein the tip lumen 72 blends smoothly into the tube lumen 70.

FIG. 1


36
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EXTRACORPOREAL CIRCULATION SYSTEM
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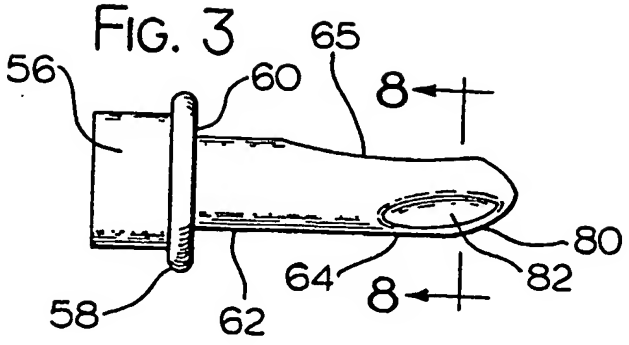
FIG. 3



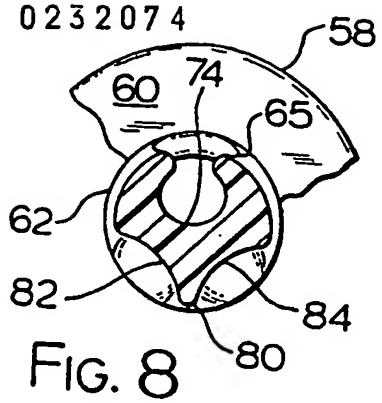


FIG. 8

FIG. 4

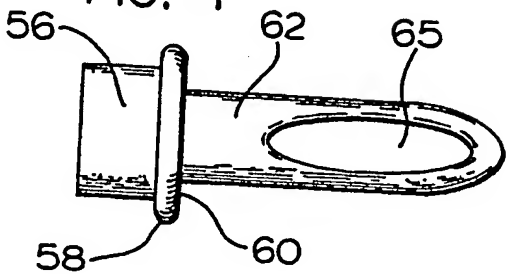


FIG. 5

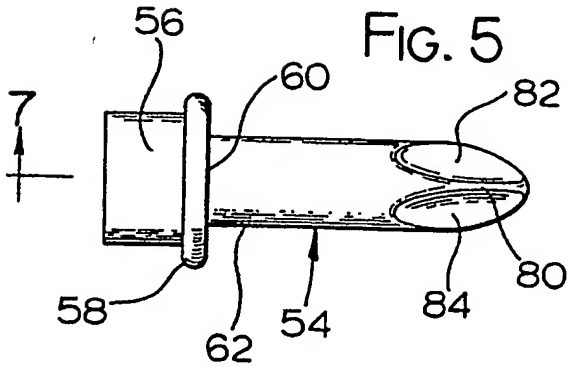
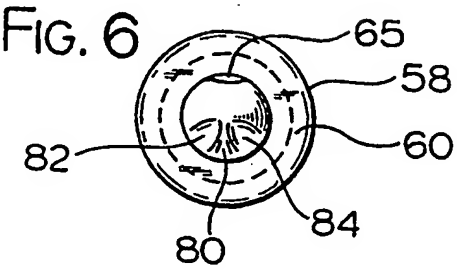


FIG. 6



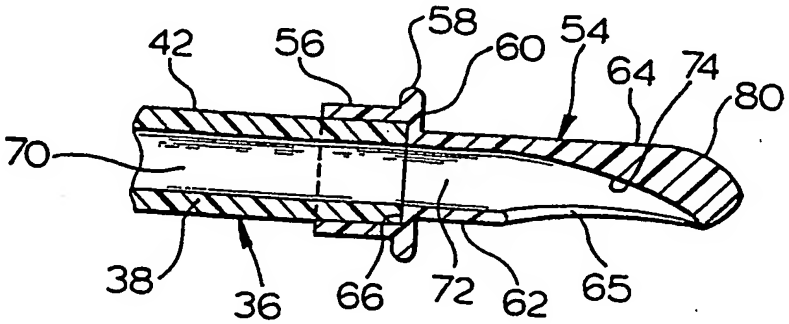


FIG. 7

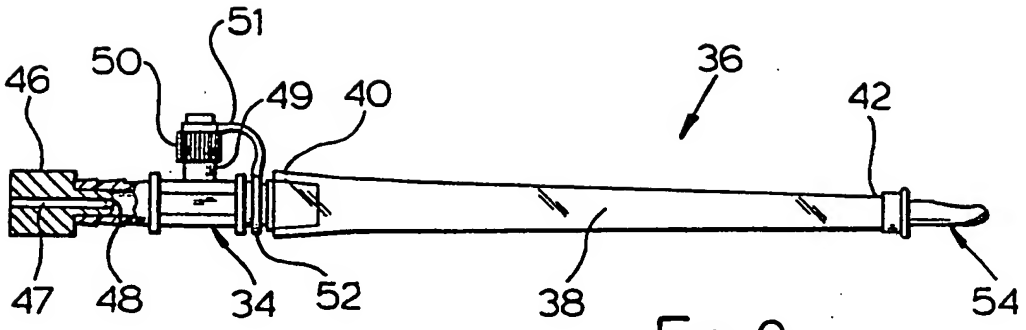


FIG. 2

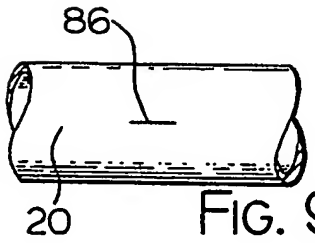


FIG. 9

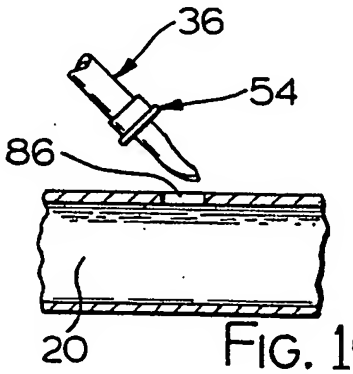


FIG. 10

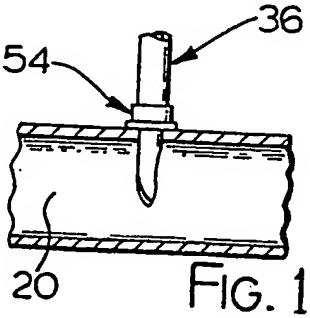


FIG. 11